1.1.10 510(k) Summary

510(k) Summary

(as required by 21 CFR 807.92 (c))

Owner's Name:

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OCT 10 2013

Classification:

Proprietary Name:	Deltex Medical CardioQ-EDM+
Common/Usual Name:	Esophageal Doppler Monitor
Classification Names:	Cardiovascular Blood Flowmeter
	Extravascular Blood Flow Probe
	Patient Transducer and electrode cable
Product Codes:	DPW, DPT, DSA
Regulation Numbers:	21 CFR 870.2100, 870.2120, 870.2900

Predicate Devices used to Demonstrate Substantial Equivalence:

The Deltex Medical CardioQ-EDM cleared on October 20, 2011 under 510(k) Number K111542

Description, including Intended Use:

The CardioQ-EDM+, is a medical instrument designed to monitor cardiac function and fluid status, providing clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward. In addition, the CardioQ-EDM+ includes a function to calculate arterial blood pressure based parameters from an output slaved from a vital signs monitor.

The CardioQ-EDM+ cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM+ beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

Comparison technological features:

The CardioQ-EDM+ has been designed by Deltex Medical as a modification to the CardioQ-EDM which received FDA clearance on October 20, 2011 under 510(k) number K111542. It uses the same product architecture but with the addition of the components, software algorithms, and display modifications that allow the CardioQ-EDM+ to calculate and display the hemodynamic parameters from the slaved pressure inputs.

The CardioQ-EDM+ combines Doppler measurement of blood flow with Pulse Pressure Waveform Analysis (PPWA). In "Flow Monitoring Mode" the system employs esophageal Doppler monitoring (EDM) techniques using 4 MHz continuous wave ultrasound to monitor and quantify the blood flow in the descending thoracic aorta, displaying this data as a maximum velocity curve, a velocity spectrum and derived measurements. Real-time information about cardiac function, in particular left ventricular flow, is displayed continuously.

From the maximum value in the velocity spectrum the following Doppler parameters are calculated: Stroke Distance (SD), Stroke Volume (SV), Stroke Volume Variation (SVV), Patient's heart rate (HR), Cardiac Output (CO), Peak Velocity (PV), Mean Acceleration (MA), Corrected Flow Time (FTc), Cardiac Index (CI), Minute Distance (MD), Systemic Vascular Resistance (SVR), Systemic Vascular Resistance Index (SVRI), Stroke Volume Index (SVI), Flow Time to Peak Velocity (FTp), Delivered Oxygen (DO_2) and Delivered Oxygen index (DO_2I).

For the CardioQ-EDM+, the newly added "Pressure Monitoring Mode" the system slaves the arterial blood pressure signal supplied by the hospital patient monitoring system to provide systolic and diastolic pressures and derived parameters.

The CardioQ-EDM+ uses these classical blood pressure measurements to calculate Stroke Volume (SV), Cardiac Output (CO), Stroke Volume Variation (SVV), Pulse Pressure Variation (PPV) and a small number of derived parameters (see below). The pressure derived stroke volume is calibrated from the CardioQ-EDM+'s Doppler ultrasound measurement of stroke volume ensuring consistency and allowing frequent recalibration.

From the Systolic and Diastolic pressures the following pressure–based parameters are calculated:

- Cardiac Output (CO),
- Cardiac Index (CI),
- Stroke Volume (SV),
- Stroke Volume Index (SVI)
- Stroke Volume Variation (SVV)
- Pulse Pressure Variation (PPV)
- Systemic Vascular Resistance (SVR),

- Systemic Vascular Resistance Index (SVRI),
- Mean Arterial Pressure (MAP)
- Heart Rate (HR)
- Delivered Oxygen (DO_2)
- Delivered Oxygen Index (DO_2I)

The CardioQ-EDM+ monitor will be supplied with a Patient Interface Cable for connecting onto a Deltex Medical probe, but not a probe or Arterial Blood Pressure Interface Lead, which must be purchased separately.

A comparison of the technological features of the proposed CardioQ-EDM+ and the predicate CardioQ-EDM is presented in the table below:

Table T1 - Technology Characteristics of New Device Compared to Predicate Device

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM (K111542) Predicate Device	**Deltex CardioQ-EDM+ Proposed Device**
Device Classification	21 CFR 870.2100, 870.2120, 870.2900 Procode DPW, DPT, DSA	21 CFR 870.2100, 870.2120, 870.2900 Procode DPW, DPT, DSA
Indications for use	The CardioQ-EDM cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM's beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward	The CardioQ-EDM+ cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM+ beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.
Patient population	For use in patients 59" (149 cm) or taller	same
Patient status	Anesthetized/sedated patients/awake	same
Insertion route	Oral or Nasal	same
Contraindications	Intra-aortic balloon pumping Severe coarctation of the aorta Pharyngo-esophago-gastric pathology Severe bleeding diatheses	same same same same
System design	Esophageal probe transmits and receives 4 MHz Continuous Wave Doppler (CWD) ultrasound to measure blood flow velocities in the descending thoracic aorta	same

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM (K111542) Predicate Device	**Deltex CardioQ-EDM+ Proposed Device**
	Signals are returned via the Patient Interface Cable (PIC) to CardioQ-EDM Monitor	same
	CardioQ-EDM Monitor processes the signal and displays it as real-time spectrum, to show the distribution of red blood cell velocities over the entire cardiac cycle	same
	Maximum velocity envelope is continuously delineated and used to calculate velocity-integral of the waveform during systole	same
	Patient age, weight & height used with velocity-integral to provide volumetric flow data, including cardiac output, from 'nomogram' calculation	same
System Components	CardioQ-EDM Monitor	CardioQ-EDM+ Monitor
	Power cord	same
	Patient Interface Cable	same
	no probes included	same
	Not required	arterial blood pressure interface lead (Not included)
Mode of operation	Continuous	same
Ultrasonic clutter rejection	450 Hz & 900 Hz high-pass filters	same
Spectral Display	512 point, Fast Fourier Transform	same
	Temporal resolution 6 ms	same
Velocity spectrum display time range (x-axis)	Full screen: 4.3 seconds Split screen: 1.4 seconds	same
Velocity display scales (y-axis)	50, 100, 200 cm/s 250 cm/s	same
Doppler audio confirmation	Yes	same
Display	Color 10.4" TFT LCD screen (800 x 600 pixels) SVGA	same
Ranges of directly measured Doppler parameters	Peak Velocity (PV) 10 – 250 cm/s	same
	Heart Rate (HR) 20 – 360 bpm	same
	Flow time (systolic) (FT)* 42 – 1500 ms	same
*not displayed (see FTc below)	Flow time to peak (FTp) 6 – 750 ms	same
	Corrected Flow Time (FTc)	same

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM (K111542) Predicate Device	**Deltex CardioQ-EDM+ Proposed Device**
	24 – 999 ms Stroke Distance (SD) 0.2 – 165 cm Mean Acceleration (MA) 0.1 – 366 m/s^2 Minute Distance (MD) 4 – 59400 cm Stroke Volume (SV) 0 – 999 ml Cardiac Output (CO) 0 - 99.9 L/min Cardiac Index (CI) 0 – 99.9 L/min/m^2 Stroke Volume Index (SVI) 0 – 99.9 L/m^2 Systemic Vascular Resistance (SVR) 0 – 9999 dyne.sec/cm^{-5} Systemic Vascular Resistance Index (SVRI) 0 – 999 dyne.sec/cm^{-5}/m^2 Not Available Not Available Not Available	same same same same same same same same Stroke Volume Variation (SVV) 0-100 % Delivered Oxygen (DO_2) 0-8040 ml/min Delivered Oxygen Index (DO_2I) 0-3965 ml/min/m^2
Ranges of pressure-based calculated parameters	Not Available Not Available Not Available Not Available Not Available	Heart Rate (HR) 20 – 360 bpm Stroke Volume (SV) 0 – 999 ml Stroke Volume Variation (SVV) 0-100 % Cardiac Output (CO) 0 - 99.9 L/min Cardiac Index (CI) 0 – 99.9 L/min/m^2 Stroke Volume Index (SVI) 0 – 99.9 L/m^2

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM (K111542) Predicate Device	**Deltex CardioQ-EDM+ Proposed Device**
	Not Available	Systemic Vascular Resistance (SVR) 0 – 9999 dyne.sec/cm^{-5}
	Not Available	Systemic Vascular Resistance Index (SVRI) 0 – 999 dyne.sec/cm^{-5}/m^2
	Not Available	Delivered Oxygen (DO_2) 0-8040 ml/min
	Not Available	Delivered Oxygen Index (DO_2I) 0-3965 ml/min/m^2
	Not Available	Systolic Pressure (Psys) 15-500 mmHg
	Not Available	Diastolic Pressure (Pdia) 0-485 mmHg
	Not Available	Mean Arterial Pressure (Pmap) 7.5-492.5 mmHg
	Not Available	Pulse Pressure Variation (PPV) 0-100 %
	Not Available	Blood Pressure (BP) 15/0 – 500/485 mmHg
Operating modes	Patient Data entry Probe Focus Run Mode	same same same
Controls & user interface	Control knob (function dependent on screen) Audio volume knob 6 'soft' buttons (function dependent on screen)	same same
Parameters displayed	Eight of the following can be displayed above the spectral display (access to all with split screen): **Doppler (Flow Monitoring Mode)** Peak Velocity (PV) Heart Rate (HR) Stroke Distance (SD) Mean Acceleration (MA) Stroke Volume (SV) Cardiac Output (CO) Minute Distance (MD) Corrected Flow Time (FTc) Flow Time to peak (FTp)	same same same same same same same same same same

PREDICATE DEVICE COMPARISON-GENERAL SYSTEM DESCRIPTION		
	Deltex CardioQ-EDM (K111542) Predicate Device	**Deltex CardioQ-EDM+ Proposed Device**
	Cardiac Index (CI) Stroke Volume Index (SVI) Systemic Vascular Resistance (SVR) Systemic Vascular Resistance Index (SVRI) **Pressure (Pressure Monitoring Mode)** Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available Not Available	same same same same same Heart Rate (HR) Stroke Volume (SV) Stroke Volume Variation (SVV) Cardiac Output (CO) Cardiac Index (CI) Stroke Volume Index (SVI) Systemic Vascular Resistance (SVR) Systemic Vascular Resistance Index (SVRI) Delivered Oxygen (DO_2) Delivered Oxygen Index (DO_2I) Systolic Pressure (Psys) Diastolic Pressure (Pdia) Mean Arterial Pressure (MAP) Pulse Pressure Variation (PPV) Blood Pressure (BP)
Parameters update rate	Every 1 to 20 heart beats	same
Trend history	Up to 240 hours/Unlimited	up to 48 hours
Trend temporal resolution	30 seconds	same
Accessories	Roll Stand Roll Stand Interface Kit Probes and Probe accessories: Deltex Medical 240 Hour Esophageal Doppler Probe (DP240) Deltex Medical 6 hour Esophageal Doppler Probe (I_2S) Deltex Medical 24 hour Esophageal Doppler Probe (I_2P) Deltex Medical 72 hour Esophageal Doppler Probe (I_2C)	same same same

Summary of Clinical and Non-Clinical Data:

Electrical Safety and Electromagnetic Compatibility:

Testing has been conducted following IEC 60601 series of standards, which are FDA recognized voluntary consensus standards.

Acoustic Output Testing:

Testing has been conducted following NEMA UD 2, which is a recognized voluntary consensus standard.

Bench Testing:

Comparative bench testing of the CardioQ-EDM+ Cardiac Function and Fluid Status Monitoring System, using a CardioQ-EDM Cardiac Output and Fluid Status Monitoring System (K111542), is included. The results of this testing supports the conclusion that the two systems have substantially equivalent performance.

Animal Testing:

No animal testing was conducted in support of this 510(k).

Clinical Testing:

No clinical testing was conducted in support of this 510(k).

Conclusions:

Based on the testing completed and the comparisons with predicate device, the CardioQ-EDM+ does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 10, 2013

Deltex Medical, Ltd.
Lawrence Brookfield
Regulatory Affairs Manager
Terminus Road
Chichester
West Sussex PO19 8TX
United Kingdom

Re: K132139
Trade/Device Name: Deltex Medical Cardioq-EDM+
Regulation Number: 21 CFR 870.2100
Regulation Name: Esophageal Doppler Monitor
Regulatory Class: Class II
Product Code: DPW
Dated: July 9, 2013
Received: July 12, 2013

Dear Lawrence Brookfield :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems

(QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.1.9 Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): To Be Assigned

Device Name: CardioQ-EDM+

Indications For Use:

The CardioQ-EDM+ cardiac function and fluid status monitoring system is designed to provide clinicians with real-time information about a patient's left ventricular blood flow and key hemodynamic parameters. The CardioQ-EDM+ beat-to-beat data on cardiovascular status can be used by the managing clinician to evaluate and optimize hemodynamic performance in anesthetized, sedated or conscious patients in the operating room, intensive care unit, emergency room or ward.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Felipe Aguel
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